

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
DAHNA PASTERNAK
ROBINS & PASTERNAK LLP
1731 EMBARCADERO ROAD, SUITE 230
PALO ALTO, CA 94303

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (day/month/year) 13 MAY 2005	
Applicant's or agent's file reference 2960/118WO	FOR FURTHER ACTION See paragraph 2 below
International application No. PCT/US04/39714	International filing date (day/month/year) 24 November 2004 (24.11.2004)
Priority date (day/month/year) 25 November 2003 (25.11.2003)	
International Patent Classification (IPC) or both national classification and IPC IPC(7): A61F 2/08 and US Cl.: 623/14.12	
Applicant COMFORMIS, INC.	

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application


2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer  Pedro Philogene Telephone No. (571) 272-4716
----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US04/39714

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US04/39714

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>NONE</u>	YES
	Claims <u>1-182</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-182</u>	NO
Industrial applicability (IA)	Claims <u>1-182</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-46 lack novelty under PCT Article 33(2) as being anticipated by Delp et al. (5,871,018).

With respect to claims 1, 46, Delp et al disclose a an implant or a kit (550) suitable for a condyle of a femur having superior and inferior surfaces (570,580), superior surface opposes the condyle and the trochlea and the inferior surface opposes at least a portion of the weight bearing portion of the tibial surface and the patella; as set forth in column 12, lines 64-67, column 13, lines 1-67, column 14, lines 1-44, wherein at least a portion of one of the superior or inferior surfaces has a three-dimensional shape that substantially matches the shape of one of the femur and the tibia surfaces; as set forth in column 11, lines 1-50.

With respect to claims 2-45, delp et al disclose all the limitations, as set forth in column 12, lines 64-67, column 13, lines 1-67, column 14, lines 1-44, column 11, lines 1-50.

Claims 47-100,169-171 lack novelty under PCT Article 33(2) as being anticipated by Eckhoff (5,728,162).

With respect to claims 47, 60, 88, 169-171, Eckhoff discloses a prosthesis device for a knee joint comprising a femoral condyle component (10) having a superior surface and an inferior surface and a top portion and bottom portion with a curved lateral edge extending therebetween; and a thrclear groove component (18) along the top portion of the device, wherein the bottom portion of the femoral condyle component terminates prior to a sulcus (20) terminalis on the joint surface, as best seen in FIGS.1,2.

With respect to claims 48-59, 61-87, 89-100, Eckhoff discloses all the limitations; as set forth in column 3, lines 5-67, column 4, lines 1-20.

Claims 101-168,172-174 lack novelty under PCT Article 33(2) as being anticipated by Turner (5,133,759).

With respect to claims 101, 135, 172-174, Turner discloses an implant system comprising a femoral component (20), wherein the femoral component replaces a femoral surface of the patellofemoral articulation surface and a tibiofemoral articulation surface, as best seen in FIGS. 7-11; and a tibial component (15), wherein the tibial component replaces a tibial surface of the tibiofemoral articulation surface; as best seen in FIGS.7-11.

With respect to claims102-134,136-168, Turner discloses all the limitations, as set best seen in FIGS.7-11, and as set forth in column 2, lines 19-67.

Claims 175-182 lack novelty under PCT Article 33(2) as being anticipated by Krakovits et al. (6,344,059).

With respect to claim 175, Krakovits et al., disclose a tibial implant (2) having a first surface having substantially planar surface and a second surface with a partially planar surface (8,9) wherein the second surface with a partially planar surface further comprises a dome structure (10).

With respect to claims 176-182, Krakovits et al disclose all the limitations; asset forth in column 3, lines 5-67, column 4, lines 25-45.

Claims 1-182 meet the criteria set out in PCT Article 33(4), and thus meet industrial applicability because the subject matter claimed can be made or used in industry.